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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/843,342

04/25/2001

Bruce L. Roberts

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06/21/2004

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EXAMINER

VANDERVEGT, FRANCOIS P

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/843,342

Applicant(s)

ROBERTS ET AL.

Examiner

F. Pierre VanderVegt

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 12-21, 23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-11, 22 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

This application claims the benefit of the filing date of provisional application 60/200,562.

New claim 25 has been added.

Claims 1-25 are currently pending.

Election/Restrictions

1. Claims 1-6, 12-21 and 23-24 stand as withdrawn pursuant to the Restriction Requirement mailed July 1, 2002.

Claims 7-11, 22 and 25 are the subject of examination in the present Office Action.

In view of Applicant's amendment and response filed March 11, 2004, only the following grounds of rejection are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 7-10, 22 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was previously stated: "Claim 7 recites the limitation of a "self-assembling fusion polypeptide wherein said fusion polypeptide (i) is capable of forming a stable homomultimer." The limitation is not supported by the specification or claims as originally filed and constitutes new matter. Applicant asserts that the amendment to the claim is supported in original claim 4, page 17, lines 26-27 and page 36, lines 3-5. Review of the specification at page 36 indicates that only the oligomerization domains form homomultimers, not the entire fusion polypeptide. It is believed that Applicant intended to recite that the oligomerization domains form homomultimers and the claims are being treated thus. However, in its present state, **the recitation constitutes new matter** and must be corrected. Dependent claims 8-10 and 22 are included in this ground of rejection."

Applicant's arguments filed March 11, 2004 have been fully considered but they are not persuasive. Applicant argues that the recitation does not constitute new matter because "the oligomerization domain of the fusion polypeptide is the portion of the polypeptide that confers the ability

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to self-assemble upon it,” reasoning that this renders the entire polypeptide a homomultimer “because it is a single polypeptide molecule.” Despite Applicant’s assertion, this does not constitute a homomultimer because the chains are not identical to one another, only the oligomerization domains are. Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The prefix “homo” is readily understood to mean “the same.” A “homomultimer” therefore, is a multimer of single units that are identical to one another, such as cadherin-11 or α -bungarotoxin, not units that have a region of homology, such as the instantly disclosed fusion polypeptides. Accordingly, the rejection is maintained.

3. Claims 7-11 stand rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

It was previously stated: “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. (See Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, especially page 1106 3rd column). A “representative number of species” means that the species that are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. MPEP 2163 II.A.3a.ii.

Claims 7-11 and 22 recite a polynucleotide, and vectors and cells comprising same, encoding a self-assembling fusion polypeptide capable of forming a stable homomultimer that comprises a T cell antigen presenting domain fused to an oligomerization domain without providing a physical structure for the polynucleotide. The genus of self-assembling polypeptides encoded by the claimed polynucleotides is therefore extremely large. Applicant has disclosed only MHC molecules as the antigen binding partner of the fusion construct and leucine zippers as the oligomerization domains which are “self-assembling” peptide segments that have a defined structure. Thus Applicant has disclosed only a limited number of “self-assembling polypeptides”. These “self-assembling polypeptides” lack a common structure essential for their function and the claims do not require any particular structure be shared by the instant “self-assembling polypeptides comprising a T cell antigen presenting domain.” It does not appear based upon the limited disclosure that Applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the limited number of species disclosed and the extensive variation permitted within the genus of “self-assembling polypeptides comprising a T cell antigen presenting domain.”

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Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material “requires a precise definition, such as by structure, formula, chemical name, or physical properties,” not a mere wish or plan for obtaining the claimed chemical invention.” Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.”

Applicant argues that the broad recitation of a “self-assembling peptide” is adequately described in the specification and that the claimed invention should not be limited to the recited example of “leucine zippers” because self-assembling peptides are well-recognized and conventional to those in the art. Applicant cites in the response several examples of self-assembling peptides to support the position. Applicant reasoned that a skilled artisan would have therefore recognized that Applicant was in possession of the full scope of “self-assembling peptides.”

Applicant’s position is not persuasive. Applicant’s argument seems to be more drawn toward enablement than description. That is, the argument seems intended to show that, following the teachings of the specification, those skilled in the art could have made the claimed polypeptides capable of forming a homomultimeric complex using oligomerization domains other than leucine zippers without undue experimentation. That is not at issue, however. The rejection is based upon a lack of adequate written description, not lack of enablement.

Applicant has pointed to nothing in the specification that rebuts the ground of rejection; i.e., a disclosure that adequately describes the genus of “self-assembling peptides” by describing a representative number of species within that genus or structural features common to that genus. In the present case, the genus of self-assembling peptides is perceived to be quite large, however Applicant has named only a single member of the genus, leucine zippers. Further, Applicant has not described any structural features of leucine zippers that are in common with any other self-assembling peptides. The property of self-assembly is a functional feature, not a structural one. Applicant’s position basically reduces down to the position that naming leucine zippers as a self-assembling peptide renders the use of all other self-assembling peptides obvious to the artisan. Applicant is reminded that entitlement to a filing date does not extend to subject matter that is not disclosed, but would be obvious over what is expressly disclosed. Lockwood v. American Airlines Inc., 41 USPQ2d 1961 (Fed. Cir. 1977). In the instant case, a “self-assembling peptide” may be obvious over leucine zippers but is not adequately described by the recitation of that single species of the genus without a further description of structural features of the species that are common to the genus to convey the desired functional feature.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 7-10, 22 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Scott et al. (J. Exp. Medicine 183:2087-2095 (May 1996); U on form PTO-892).

It was previously stated: "Scott et al teaches a polynucleotide which encodes a fusion polypeptide comprising an extracellular domain of a murine IA Class II MHC alpha chain, which contains a T cell antigen presenting domain, and an oligomerization domain which can form a stable homomultimer. Scott teaches a second fusion polypeptide comprising an extracellular domain of a murine IA Class II MHC alpha chain, which contains a T cell antigen-presenting domain, and an oligomerization domain which can form a stable homomultimer, as recited in claim 7 (see entire article, especially the Summary). Scott teaches the gene delivery vehicle pRMHa3 vector comprising the polynucleotide (page 2088, first column in particular) [claim 8] and SC2 host cells comprising the polynucleotide [claim 9] and the polypeptide expressed from the polynucleotide (ibid) [claim 10]. Said fusion protein taught by Scott et al comprises a leucine zipper domain as the oligomerization domain as recited by claim 22 (see entire article, especially the Summary). The prior art anticipates the claimed invention."

Applicant argues that the Scott reference is not applicable as prior art because Scott teaches only a heteromultimer, while the present claims are specifically drawn to a homomultimer. However, as pointed out supra, Applicant put forth the position that a fusion polypeptide comprising a self-assembling oligomerization domain that is capable of self-association renders the entire fusion polypeptide homomeric to its counterpart fused to a corresponding oligomerization domain (pages 4-5 of response filed March 11, 2004 for example). Applicant's lone example of such an oligomerization domain is a leucine zipper. Because Scott also used a leucine zipper to join the subunits of the taught multimeric complex, the subunits and complex of Scott effectively satisfy the metes and bounds of the claims because Scott's "entire polypeptide forms a homomultimer as a result of the oligomerization domain because it is a single polypeptide" (page 5, paragraph 1 of response filed March 11, 2004 for example).

Conclusion

5. No claim is allowed.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (571) 272-0852. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

F. Pierre VanderVegt, Ph.D. *PV*
Patent Examiner
June 17, 2004

Patrick J. Nolan
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PRIMARY EXAMINER
6/17/04